K102121
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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 12 2011

Date Prepared: November 29, 2010

Submitter Information:

Submitter's Name:	Apollo Spine
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Device Trade Name: Eclipse Vertebral Spacer-Lumbar

Common/Usual Name: Intervertebral body fusion device

Classification: 21 CFR §888.3080

Class: II

Product Code: MAX, MQP

Intended Use:

When used as an Intervertebral Body Fusion System:

The Eclipse Vertebral Spacer System-Lumbar is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine with accompanying radicular symptoms at one disc level from L2-S1. DDD is defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have completed six weeks of non-operative treatment. The Eclipse Vertebral Spacer System-Lumbar implants are to be used with autogenous bone graft. Supplemental fixation is required.

When used as a Vertebral Body Replacement Device:

The Eclipse Vertebral Spacer System-Lumbar when used as a vertebral body replacement is intended for use for partial and total replacement of a vertebral body that has been resected or excised due to tumor and/or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine at a single level from

T1-L5. These devices are intended to be used with autogenous bone graft. Supplemental fixation is required.

Device Description and Technological Characteristics:
The Eclipse Vertebral Spacer-Lumbar acts as a spacer to maintain proper Intervertebral and vertebral body spacing and angulation. The Eclipse Vertebral Spacer is manufactured from PEEK, unalloyed titanium, and Ti6Al4V titanium alloy. The device contains serrations on the superior and inferior surfaces and includes positioning pins that are advanced during placement. Pins are used to aid in the positioning and to allow for radiographic confirmation during device placement.

Predicate Device(s):
The Eclipse Vertebral Spacer-Lumbar was shown to be substantially equivalent to previously cleared devices and had the same indications for use, design, materials, and performance.

Nonclinical Testing Summary and Conclusion:

The substantial equivalence is supported by nonclinical bench testing. Tests were selected in accordance with those described in FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." The specific testing completed is detailed as follows:

- Static Compression (per ASTM 2077)
- Dynamic Compression (per ASTM 2077)
- Static Compression Shear (per ASTM 2077)
- Dynamic Compression Shear (per ASTM 2077)
- Subsidence (per ASTM 2267)
- Analysis of wear debris generated during dynamic testing

Test results for each of the above studies confirm that the Eclipse Vertebral Spacer is substantially equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Apollo Spine
% STD Medical, Inc.
Ms. Christine Santagate
3700 Campus Drive, Suite 105
Newport Beach, California 92660

SEP 12 2011

Re: K102121
Trade/Device Name: Eclipse Vertebral Spacer System-Lumbar
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MQP
Dated: December 14, 2010
Received: December 20, 2010

Dear Ms. Santagate:

This letter corrects our substantially equivalent letter of January 12, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102121

Device Name: Eclipse Vertebral Spacer System-Lumbar

JAN 12 2011

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Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102121